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Integration Evaluation of the Advanced Mission Extender Device Max

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United States Army Aeromedical Research Laboratory

Warfighter Protection Division

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14. ABSTRACT

The Advanced Mission Extender Device Max (AMXD max) was developed by Omni Measurement Systems, Inc. to provide an improved in-flight urination capability for military aviators. Four participants underwent training, familiarization, and integration assessments in a UH-60 simulator and aircraft, a CH-47, and AH-64, whilst wearing U.S. Army operational ALSE. Overall, the AMXD max was rated as either 'acceptable' (31.5 percent) or 'completely acceptable - no improvements needed' (68.5 percent) in all phases of this study. The device will not accommodate all anthropometric sizes, but should fit 90 percent of male aircrew and up to 95 percent of female aircrew. The key integration issue concerned the potential for urine collection bag damage and rupture in the underside of aircrew seats both the UH-60 and AH-64. It is probable that this issue could be overcome by use of the alternative shorter urine collecting tubes, and polymer-filled disposable urine collection bags. Once the integration issues are resolved this system has strong potential to improve crew comfort and endurance on U.S. Army rotary wing aircraft.

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Introduction

Currently, there is no approved in-flight aircrew bladder relief system in the U.S. Army, and aircrew resort to options, such as soft drink bottles, that are less than optimal for providing safe, effective relief in the operational environment. These options are awkward to use in a seated position, requiring release of restraint harnesses and change of body position, and do not provide a suitable solution for female aircrew. There is also no approved system for use when wearing chemical/biological protective suits. The lack of adequate effective bladder relief systems for both male and female aircrew has resulted in some individuals choosing to dehydrate prior to and during flight, in order to avoid the use of the current ad hoc devices. This voluntary dehydration can increase aircrew susceptibility to heat stress, urinary tract infection, and renal calculi, and can impair alertness and potentiate fatigue. A recent study (Lindseth, Lindseth, Petros, Jensen, & Caspers, 2013) found that flight performance and spatial cognition scores were significantly poorer for pilots who had low fluid intakes and experienced dehydration, in comparison to hydrated pilots. An improved bladder relief system would reduce the temptation for aircrew to dehydrate deliberately.

The Advanced Mission Extender Device Max (AMXDmax®) was developed by Omni Measurement Systems, Inc., under a Small Business Innovative Research Project with the U.S. Air Force (USAF), to provide an improved system for in flight urinary relief for male and female aircrew. The system uses a portable pump technology to provide an easier to use, more effective bladder relief system. Until the development of the AMXDmax®, USAF aircrew would use commercially available unisex bags filled with polymer that turned to a semi-solid, non-spillable gel when wet. These devices, such as the TravelJohn™ used by the British rotary wing aircrew, do provide a unisex solution and are cheap, but require handover of flight controls and restraint harness release before use.

Background

The original AMXD® was developed from an initial concept in 2002 by Omni Measurement Systems, Inc., under an SBIR with USAF, and received airworthiness clearance on all USAF aircraft in November 2006 (United States Air Force [USAF], 2006b). The system also received Federal Drug Administration (FDA) approval in 2006 with no caveats about duration of use or warnings about any side-effects of use (Food and Drug Administration [FDA], 2013). In 2008, the U.S. Navy Naval Air Systems Command (NAVAIR) (PMA) 202 certified the AMXD® on all U.S. Navy (USN) aircraft. Design modifications were made in 2009 following feedback from aviators (Omni Medical Systems, 2010). This version was designated AMXDmax® and received Safe-to-Fly (STF) certification from both the USN and USAF in 2009. The upgrades to the AMXDmax® included more automation, improvements to battery life, male cup comfort and collection bag design, plus a reduction in device size. A particular driver for these changes was to reduce cost by making more elements re-usable. The collection bag was originally disposable and filled with polymer similar to that in the TravelJohn™. The replacement, however, was a re-usable liquid collection bag. The system has been used in a variety of fast jet aircraft including A-10, F-15, F-16 and F-18, and approximately 1100 items have so far been fielded by the USAF and USN. According to the manufacturer's website, the system has been procured also by the

Dutch and German air forces. It has also been used in rotary wing (RW) aircraft including the U.S. military HH-60, and the Dutch CH-47 and AH-64D. Ground-based trials during which participants continuously sat in UH-60 seats for up to 16 hours have been conducted, and there are reports from the manufacturer of up to 14 hours continuous use by military aircrew (Omni Medical Systems, 2010).

Although AMXD® received very high acceptability ratings during development trials, it has not been possible to identify any independent military trials of the in-service effectiveness of the AMXDmax® in rotary wing aircraft. The authors of this report were contacted by one male HH-60M pilot from the Vermont National Guard, who had used the system in-flight in 2010, and he reported no integration issues and no flight safety concerns (personal communication, March 15, 2013).

There is evidence of the safety and lack of side-effects with long-term use of AMXDmax® by the civilian community, where AMXDmax® has been used in spinal cord injured patients. One study from the University of Vermont reported on three such cases, in which the patient used the system for up to 8 hours per day over a period of one month (Plante and Walker, undated). There were no reported system failures or side-effects, and the device achieved a 100% acceptability rating for comfort.

Objective

The U.S. Army Medical Research and Materiel Command (USAMRMC) requested that the U.S. Army Aeromedical Research Laboratory (USAARL) conduct test and evaluation (T&E) of the AMXDmax®. The objective of this evaluation was to assess the acceptability of the AMXD max®, for use with Army Aviation Life Support Equipment (ALSE) in a variety of rotary wing aircraft. In view of the supporting evidence of successful function in military aircrew during the development of the system, the subsequent STF clearances for both the USAF and USN, and the FDA approval, the actual function of the AMXDmax® as a urine collection device was not in question. Therefore, this was planned as a ground-based ALSE and aircraft integration assessment only.

Materials and methods

AMXD max®

The AMXDmax® systems to be tested were provided by the manufacturer, at the request of U.S. Army Medical Materiel Development Activity (USAMMDA). The system consisted of a re-usable male cup manufactured from medical grade polyurethane (figure 1), and a re-usable female pad (figure 2). Modified male and female undergarments in two sizes, manufactured from natural fibre, were provided. The male undergarment incorporated a cup housing pouch and an exit position for the collecting pipe (figure 3). The female undergarment was of sufficient dimensions to allow the pad assembly to be located securely with adhesive tape. There was a

portable control unit (pump unit) (figure 4), with associated charger attachments, and a 1.2 liter re-usable urine collection bag (figure 5).

Figure 1. AMXD max male cup.

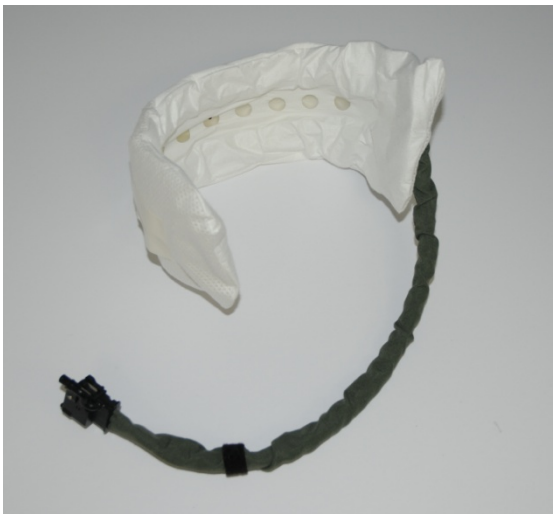

Figure 2. AMXD max female pad.

Figure 3. Male under garments provided with AMXD max.

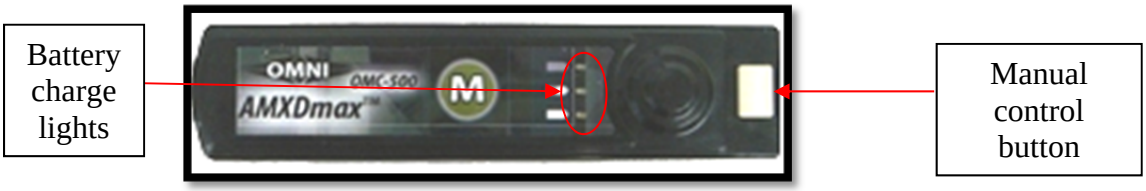

Figure 4. AMXD max control unit.

Figure 5. 1.2 liter urine collection bag.

The male cup was provided in one size, the IMC-2, which was designed to accommodate the USAF aircrew population with the minimum number of sizes (USAF, 2006a). According to the

manufacturer, it was found during USAF trials that 90% of male aircrew could be accommodated with this size cup (M. Harvie, personal communication, May 7, 2013). The female pad was provided in two sizes, the IFP-1 and IFP-2, which were determined by USAF to fit 95% of the females flying ejection seat aircraft (M. Harvie, personal communication, May 7, 2013). Both cup and pad have attached an 18-inch (45.7 cm) long, Nomex® covered, flexible hose, with a quick-disconnect plug on one end for connection to the portable pump.

The system is designed to operate automatically when the pump and bag have been connected to the flexible collection hose. In the female version, connection of the pump automatically initiates, over a period of 20 to 30 seconds, full-inflation of the outer edges of the female pad to create a seal. In both devices, moisture detection sensors placed inside the male cup and female pad, activate the pump when urine is detected and the urine is drawn into the bag via the collecting hose and pump.

The control pump has three, green light-emitting diodes (LED) to indicate battery life availability. No on/off switch is required as the pump unit becomes active upon connection to the collecting hose. A manual button is provided to switch on the pump if required. After use in this test, each item was washed out and re-used or disposed of, by participants in accordance with the training instructions.

On the basis of the existing evidence presented above, including the un-caveated FDA approval, it was determined that there would be no requirement to replicate long duration tests of the AMXDmax®. The system has been shown to function correctly for prolonged periods and there are no published concerns regarding side effects. Furthermore, as the functional ability of the system to safely collect urine whilst strapped into military aircraft seats was also not in question, it was determined that successful urination during any phase of the current test was not critical to the overall assessment.

Four USAARL volunteer personnel, two male and two female, were selected to participate in the test based on their broad range of anthropometry. Both of the male participants were rated Army aviators, but the female subjects were not. None of the participants had any previous experience with using the AMXDmax®. All participants were medically screened by the study physician prior to undertaking the trial, to ensure they were not suffering from any of the following: diabetes mellitus, hypertension, renal disease, frequent urinary tract infection (UTIs), any current yeast infection, recent history of heat illness, active skin disorders, or current pregnancy.

This study was reviewed by the USAARL Regulatory Compliance Officer and was determined to be a non-research test.

Anthropometry

The height and weight of the participants were assessed against the 1988 Anthropometry Survey of U.S. Army Pilots (Donelson & Gordon, 1988), as displayed in table 1.

Table 1.
Anthropometric distribution of participants.

Subject Number	Sex	Height (ins)	Centile (%)	Weight (lbs)	Centile (%)
1	Male	71	70	175	50
2	Male	67	15	205	90
3	Female	67	70	161	82
4	Female	61	1	114	4

Test Plan

Phase 1: Training

The participants were briefed on the test plan and issued a fact sheet providing information about the equipment and the test design. They were also issued a DVD containing a copy of the on-line training video provided by Omni Measurement Systems. The training videos were shown by the study physician and principal investigator (PI) to the participants, and use of the equipment was demonstrated. All participants were then advised to review the training DVD during their own time, and to familiarize themselves with the AMXDmax®. This included use of the device at home and in an office environment for a period of two days, or for as long as was required for each participant to be comfortable, competent and confident in the use of the equipment. At the end of the ground familiarization and training period a questionnaire was completed by each participant. For simplicity, the same questionnaire (appendix A) was used for all subsequent phases of the test, with participants completing the appropriate sections as required.

Phase 2: Integration of the AMXD with operational ALSE

Each participant donned the AMXDmax®, and integration with current operational ALSE, including body armor, was assessed by the test team and observations were noted. At the end of this phase, each participant completed a questionnaire.

Phase 3: NUH-60FS Simulator assessment

Each participant was asked to conduct an identical sortie profile in the NUH-60FS simulator at USAARL whilst wearing the AMXDmax®. Participants occupied either the left or right pilot's seat, stowing the collection bag beside the seat on the right side. Each participant flew the aircraft using all primary flight controls. In accordance with the training video, the collection

bag was stowed when not required. A simulated bag change, using a second collection bag filled with water, was conducted under low cockpit light conditions. Participants were at liberty to urinate during the simulated sortie if required. Each sortie lasted approximately 25 minutes. At the end of this phase each participant completed the appropriate sections of the questionnaire.

Phase 4: Aircraft integration assessments

A standard integration assessment was conducted by all participants in a static UH-60L. The assessment was conducted in accordance with the protocol located in appendix B, and involved simulated pre-flight walk around, ingress, strapping-in procedures, cockpit maneuvers, and both standard and emergency egress. Participants were at liberty to urinate whilst strapped into the aircraft. A simulated in-flight urine collection bag change was also conducted using a collection bag filled with water. All participants completed the relevant sections of the questionnaire.

It was determined from the UH-60L integration assessment that there were no gender specific issues with the AMXDmax®, and so, for logistic reasons, only the two male subjects took part in the integration assessments on the AH-64D and CH-47. After each integration, participants completed the relevant sections of the questionnaire.

Phase 5: 7-day follow-up

A follow-up questionnaire (appendix C), was completed by all participants 7 days after the end of the test, to determine whether or not any residual side-effects had occurred from wearing the AMXDmax®.

Safety

Participants self-reported as fully nourished and hydrated before starting any of the test phases. The urine bags were drained into toilets and the bags were placed in clinical waste containers at the end of the test.

Results

Phase 1: Training

The mean hours of device usage during this phase was 4.25 hours (range: 1-11 hours). The female participants had the higher usage time of 7.5 hours mean (range: 4-11 hours), whilst the men had one hour usage each.

Both male participants chose to practice whilst wearing A2CU, Air Warrior Vest and extraction harness. One of these complained of tightness due to the lack of spare space in the crotch of the A2CU pants. One female subject noted awkwardness in becoming accustomed to the device. There were positive comments from all participants regarding the short training and familiarization requirements. The cumulative rating scores for comfort and functionality in this

phase are noted in table 2. Two participants did not attempt to use the device for urine collection during this phase.

Table 2.
Phase 1: comfort and functionality cumulative rating scores (figures indicate number of participants rating at each level, $n = 4$).

Criteria	Completely Unacceptable	Unacceptable with Recommendation of Improvement	Acceptable	Completely Acceptable No Improvement Needed	N/A
Ease of use of the AMXD[1]			**2**	**2**	
Reliability in urine collection				**2**	**2**
Adequacy of training			**1**	**3**	
Fit of AMXD			**2**	**2**	

Phase 2: Integration of the AMXD with operational ALSE

The AMXDmax® was integrated with full operational ALSE including A2CU, Air Warrior Vest Gen III, extraction harness, and body armor. The collection tube was routed out through the zipper. The mean duration of device usage in this phase was 1.3 hours (range: 0.25-2 hours). The issues noted were minimal pinching in the crotch due to the associated ALSE, and some discomfort associated with the weight of the body armor pressing down on the device. It was also noted by one female participant that it was difficult to pull out the hose from inside the A2CU pants when wearing the complete clothing assembly. The cumulative rating scores for comfort and functionality in this phase are noted in table 3.

[1] This question in all phases related to the overall ease of use of the AMXDmax® device, such as donning and doffing, connecting and disconnecting of urine collection bags, and urination if it was attempted. Successful urination was not required to achieve an acceptable score as this was not a primary requirement of this equipment evaluation.

Table 3.
Phase 2: comfort and functionality cumulative rating scores (figures indicate number of participants rating at each level, $n = 4$).

Criteria	Completely Unacceptable	Unacceptable with Recommendation of Improvement	Acceptable	Completely Acceptable No Improvement Needed	N/A
Ease of use of the AMXD			**1**	**3**	
Reliability in urine collection			**1**	**2**	**1**
Adequacy of training			**1**	**3**	
Fit of AMXD			**1**	**3**	

Phase 3: NUH-60FS Simulator assessment

All four participants took part in this phase occupying either the left or right seat of the NUH-60FS simulator, whilst wearing complete operational ALSE except for ammunition and flight helmet. The mean duration of device usage during this phase was 1.85 hours (range: 0.4-4 hours). The simulator is fitted with ARA, Inc. energy attenuating aircrew seats. There were no issues with strapping in, and the collection tubes were routed over the top of the right lap strap and to the right side, away from the collective control lever. The pump and collection bags were disconnected and stowed in door pockets when not in use. When in use, the collection bags were left to hang on the right side of the participant. All participants conducted pump and bag connections successfully in low-light conditions. Three of the participants urinated successfully whilst in the simulator. The female subjects noted the following issues.

a. Prior to strapping in, deploying the collecting tube from the A2CU pants whilst seated and wearing operational ALSE, was difficult.

b. There was a need to reposition in the seat to ensure full inflation of the device, prior to urination.

c. The device did not start pumping immediately and so there was need to control urine flow rate initially.

d. One of the participants noted an odor of urine from a vent on the collection bag, which was unexpected as it was not mentioned in the training package. No leakage of urine occurred.

One of the male participants was unable to urinate in the seated position despite loosening the restraint harness. This was not due to any design problems with the AMXDmax®, rather a reflection of his self-reported inability to urinate whilst in a seated position throughout his flying career. The other male participant noted that it was more difficult to urinate into the device whilst seated than when standing. One male subject also noted after several hours of use, some irritation of the glans penis. This did not require medical treatment, resolved spontaneously in

less than 12 hours, and did not recur during subsequent test phases. The cumulative rating scores for comfort and functionality in this phase are noted in table 4.

Table 4.
Phase 3: comfort and functionality cumulative rating scores (figures indicate number of participants rating at each level, $n = 4$).

Criteria	Completely Unacceptable	Unacceptable with Recommendation of Improvement	Acceptable	Completely Acceptable No Improvement Needed	N/A
Ease of use of the AMXD			**1**	**3**	
Comfort of the AMXD cup during flight			**1**	**3**	
Reliability in urine collection			**1**	**2**	**1**
The impact of the system on situation awareness			**1**	**3**	
Adequacy of training			**1**	**3**	
Fit of AMXD			**1**	**3**	
Ease of changing bags during flight			**1**	**3**	

Phase 4: UH-60 integration assessments

Integration into the UH-60 aircraft was conducted whilst wearing complete operational ALSE except for ammunition, and no weapons were mounted in the aircraft. The mean number of hours use of the device during this phase was 3.1 hours (range: 1.5-6 hours). There were no issues with pre-flight walk around or strapping in. However, again, participants noted that it was difficult to deploy the collecting tube from the zipper of the A2CU pants, when seated and wearing operational ALSE.

The pump and collection bags were stowed in door pockets when not in use. The collection tubes were routed to the right side, away from the collective control lever, and participants noted that in the left seat the plastic clip on the end of the collecting tube was potentially vulnerable to damage from a mounted weapon on that side. When the pump and bag were connected, the collection bags were allowed to hang on the right side of the participant. On the right seat, there were sharp edges, and the seat height adjustment lever under the seat pan that presented a potential snagging hazard, and also could result in tears in the bag (see figure 6 and 7). The resultant leakage of urine would be onto electronics housed in the space beneath the seat. It

should be noted that whilst this aircraft was fitted with seats manufactured by ARA, Inc., similar issues would exist in aircraft fitted with the alternative seat manufactured by Simula, Inc.

Figure 6. Potential tube and bag snagging and damage hazard under UH-60 right pilot seat pan.

Figure 7. Potential tube and bag snagging and damage hazard on the height adjustment lever under the UH-60 right pilot seat pan.

Also, participants noted that during a bag change, or when disconnecting after in-flight urination to stow the pump and bag, a few drops of urine were noted to fall from the end of the collecting tube. Again, this was a concern due to the location of vulnerable electronics under the right seat. The instruction manual and training video recommend that after each urination cycle is complete, the pump and bag be disconnected and stowed. Whilst this is not essential for male users, it is required for females to allow the device to deflate. Three of the four participants were able to urinate whilst strapped into the aircraft, with one male participant again not able to do so for the reasons discussed previously. Both female participants noted a feeling of "not being completely dry" after use of the device in the aircraft. One of the female units malfunctioned and failed to inflate or provide suction, due to a loss of battery charge. Cockpit activities, normal and emergency egress were all conducted without difficulty. Crew chief seat integration was unremarkable. The cumulative rating scores for comfort and functionality in this phase are noted in table 5.

Table 5.
Phase 4: UH-60 comfort and functionality cumulative rating scores (figures indicate number of participants rating at each level, $n = 4$).

Criteria	Completely Unacceptable	Unacceptable with Recommendation of Improvement	Acceptable	Completely Acceptable No Improvement Needed	N/A
Ease of use of the AMXD			**3**	**1**	
Comfort of the AMXD cup during flight			**3**	**1**	
Reliability in urine collection			**2**	**1**	**1**
The impact of the system on situation awareness			**1**	**3**	
Adequacy of training			**1**	**3**	
Fit of AMXD			**2**	**2**	
Ease of changing bags during flight			**1**	**3**	

Phase 4: AH-64 integration assessments

One male subject conducted the AH-64 integration, and assessed the device while seated in both front and rear cockpits. Operational ALSE was worn except for ammunition and flight helmet. Total time for this phase was 0.5 hours. There were no issues with pre-flight walk around or strapping in. The collection tubes were routed to the right side, away from the collective control lever. When the pump and bag were connected, the collection bags were allowed to hang on the right side of the participant. In the front seat, with the seat fully down, the gap between the airframe and the seat was very restricted but sufficient for the bag and tube to snag (figure 8). This would present a potential problem during emergency egress, delaying evacuation of the aircraft, and possibly some minor localised trauma in male aircrew due to the urine collection cup design. In the rear cockpit, there were no such snagging issues but, as with the UH-60, there were sharp edges beneath the seat which could cause damage or tearing of the collecting bag. The collecting tube and bag could also be trapped and damaged during raising and lowering of the seat, or with the downward seat stroking that may occur in a mishap. Cockpit activities, normal and emergency egress were all conducted without difficulty.

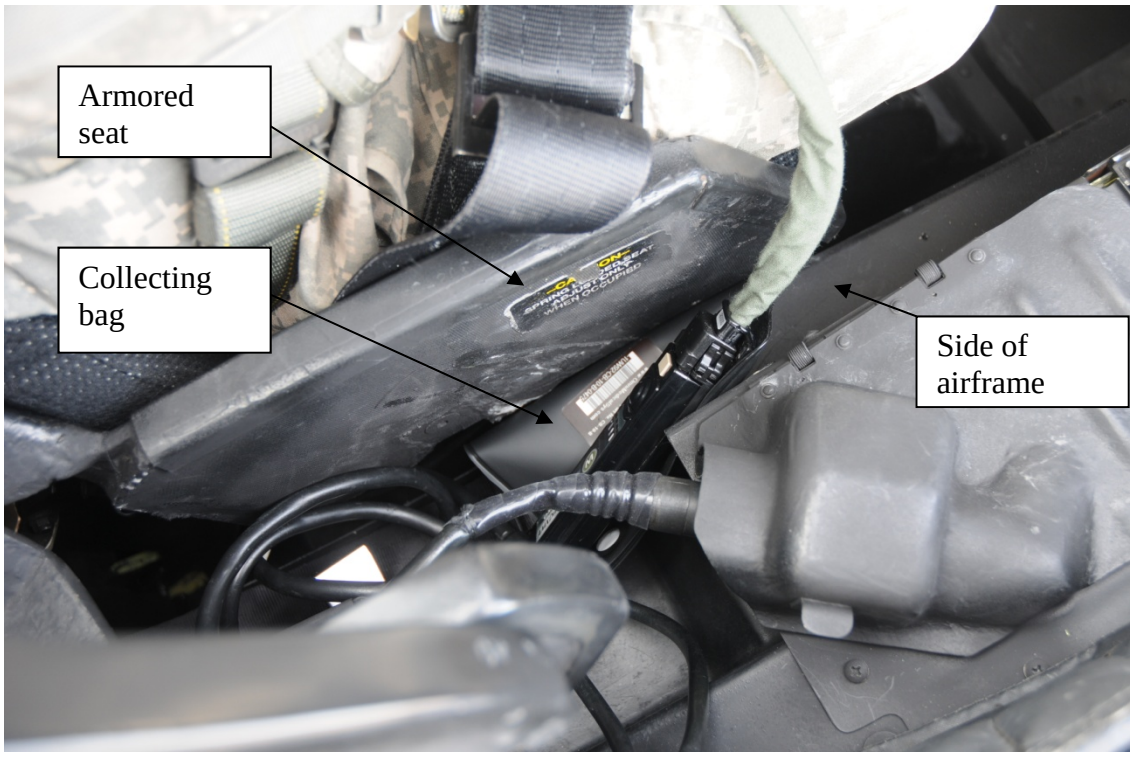

Figure 8. Collecting bag trapped between armored AH-64 front seat and side of airframe.

The rating scores for comfort and functionality in this phase are noted in table 6. The N/A rating reflects the fact that the participant did not urinate during the assessment.

Table 6.
Phase 4: AH-64 comfort and functionality cumulative rating scores (figures indicate number of participants rating at each level, $n = 1$).

Criteria	Completely Unacceptable	Unacceptable with Recommendation of Improvement	Acceptable	Completely Acceptable No Improvement Needed	N/A
Ease of use of the AMXD				**1**	
Comfort of the AMXD cup during flight				**1**	
Reliability in urine collection					**1**
The impact of the system on situation awareness				**1**	
Adequacy of training				**1**	
Fit of AMXD				**1**	
Ease of changing bags during flight				**1**	

Phase 4: CH-47 integration assessments

One male subject conducted the CH-47 integration, and assessed the device while seated in each pilot seat. Operational ALSE was worn except for ammunition and flight helmet. Total time for this phase was 0.5 hours. There were no issues with pre-flight walk around. Strapping in was less comfortable than on other aircraft due to the design in this aircraft with a wider lap belt, 4-point harness, and bulky lever style buckle, all of which applied pressure over the device (figure 9). The collection tubes were routed to the right side, away from the collective control lever. When the pump and bag were connected, the collection bags were allowed to hang on the right side of the participant. Cockpit activities, normal and emergency egress were all conducted without difficulty.

Figure 9. Pressure on collecting tube due to restraint harness design in left pilot seat of CH-47.

The rating scores for comfort and functionality in this phase are noted in table 7. The N/A rating reflects the fact that the participant did not urinate during the assessment.

Table 7.
Phase 4: CH-47 comfort and functionality cumulative rating scores (figures indicate number of participants rating at each level, $n = 1$).

Criteria	Completely Unacceptable	Unacceptable with Recommendation of Improvement	Acceptable	Completely Acceptable No Improvement Needed	N/A
Ease of use of the AMXD				**1**	
Comfort of the AMXD cup during flight			**1**		
Reliability in urine collection					**1**
The impact of the system on situation awareness				**1**	
Adequacy of training				**1**	
Fit of AMXD				**1**	
Ease of changing bags during flight				**1**	

Phase 5: 7-day follow-up

One female subject noted skin irritation and a rash which lasted for less than one day after completing Phase 4, which was determined to be primarily a sizing issue. No medical treatment was required. All participants felt that AMXD max was a good or useful device, and would be prepared to use it operationally in the air, given the appropriate airworthiness clearances.

Other issues

There were issues with equipment failure mostly relating to batteries failing to charge, or to hold charge for sufficient time. Battery failure renders the device inoperable. Mean total usage time over all phases was 10.5 hours (range: 7-18 hours).

Summary of comfort and functionality ratings

A summary of the cumulative comfort and functionality scores for all phases is presented as a percentage in table 8. The percentage assessments do not include the non-applicability scores assigned to the question on "Reliability in urine collection," as no assessment of function was provided by these participants.

Table 8.
Comfort and functionality cumulative rating percentages for all phases.

Criteria	Completely Unacceptable (%)	Unacceptable with Recommendation of Improvement (%)	Acceptable (%)	Completely Acceptable - No Improvement Needed (%)
Ease of use of the AMXD	0	0	38.9	61.1
Comfort of the AMXD cup during flight	0	0	50.0	50.0
Reliability in urine collection	0	0	36.4	63.6
The impact of the system on situation awareness	0	0	20.0	80.0
Adequacy of training	0	0	22.2	77.8
Fit of AMXD	0	0	33.3	66.7
Ease of changing bags during flight	0	0	20.0	80.0
Mean overall %	**0**	**0**	**31.5**	**68.5**

Discussion

Overall, the AMXD max was rated as 'acceptable' or 'completely acceptable - no improvements needed' in all phases of this study, with a strong bias of 68.5% towards the latter. A broad anthropometric participant range was covered, 1st percentile female to 70th percentile male for stature, and 4th female to 90th male for weight. Familiarization and training times varied considerably between the male and female participants, in line with the more complex nature of the female version of the device. However, the low usage time in this phase by the male participants is perhaps reflected in some of the issues noted in subsequent phases. Reassuringly, both female and one male participant were able to urinate when strapped into the simulator and aircraft, confirming that the training burden is low. One male participant was unable to urinate into the device whilst seated, but was successful when standing. As this participant reported that he has never been able to urinate in a seated position, the design of AMXDmax® is not at fault in this case. However, this does highlight the fact that this device will not be suitable for all aviators.

Side effects were noted by two participants. The single case of mild glans irritation after prolonged wearing of the device on the ground during Phase 3, resolved spontaneously within 12 hours and there was no recurrence in subsequent test phases. This issue has been noted before by

the manufacturer. The original USAF procurement specification required 'one size fits all' for males, and as the IMC-2 Male Cup was demonstrated to fit 90% of the USAF males aircrew, it was deemed acceptable and no other size was developed. It is likely that the current male cup will also fit approximately 90% of U.S. Army aircrew, and a greater anthropometric range would require development of an alternative cup size.

The IFP-1 and IFP-2 were determined during USAF trials to fit 95% of the females flying ejection seat aircraft, and so the irritation reported by one female participant was most probably due to her being below the 5th percentile for stature, and thus below the acceptable stature for ejection seat aircraft.

Equipment reliability, which seemed to relate to battery charge failures or poor battery endurance, below the advertised endurance figures was an issue during the tests. The faulty units will be returned to the manufacturer.

In Phase 1 of testing, participants reported that there was not adequate spare capacity in the crotch area of the male A2CU pants, to accommodate the extra bulk of the AMXDmax®. This could be overcome by aircrew using a larger size of pant, although this would add to the cost of fielding the device.

Whilst wearing the AMXDmax® on the ground, during pre-flight aircraft walk around, and before connecting the pump and bag, the training video recommends that the tube be tucked into the front of the pants behind the closed zipper, to prevent snagging and to preserve modesty. In Phase 2 and other phases, participants noted that it was difficult to retrieve the tube from this position, particularly when seated. It is likely that training and experience would alleviate this problem for most users, but also this would be helped by wearing a larger size of A2CU pant.

During Phase 3 in the NUH-60FS there were no issues with seat and cockpit integration, operating the equipment in low light, or NVG compatibility. Female users were required to disconnect the control unit and bag after each use, as per instructions. The test participants reported that they had to reposition themselves in the seat to allow for full inflation of the device each time it was used, which was a distraction. This issue has been discussed with the manufacturer who suggested that increased familiarity with the device would alleviate such issues. However, it was also noted that the pressure in the devices was set for ejection seat aircraft, and that some trials have been done with reduced inflation pressure that would allow the device to remain inflated and comfortable throughout a mission. According to the manufacturer, they have conducted successful in-house trials at half of the current inflation pressure for 8 hours duration. This could be explored as an option for U.S. Army aircrew.

The female participants also reported that the device did not start pumping immediately on initiation of voiding, and that there was a need to control urine flow initially. This was perhaps a training and pad positioning issue according to the manufacturer. One female participant noted a urine odor, which had not been expected, on voiding. There is a hydro-block air filter attached to the bag to reduce but not eliminate such odors. This finding has been discussed with the manufacturer, who has undertaken to review the training manual to reflect this. Such odors

might also be reduced or eliminated by the use of polymer-filled collection disposable bags rather than standard liquid re-usable collection bags.

In Phase 4, the integration issues related to the vulnerability to damage of the plastic clip on the end of the collecting tube, and also the potential for the bag to be damaged by sharp edges under the seat. Some form of protection for this clip might be required. Alternatively use of a 12-inch (30.5 cm) tubing length, which is available, would probably solve the problem but will require testing. Also, the use of the polymer-filled collecting bags would prevent liquid spillage in the event of collecting bag damage. Small drips emanating from the end of the collecting tube were noted during bag changes, and there were concerns expressed about vulnerable electronics beneath the right seat in the UH-60. According to the baseline risk assessment prior to initial flight tests, the design requirement was for less than 3 milliliters (ml) of liquid spillage while flying high performance aircraft (USAF, 2006a). The spillage during this trial was not measured, but no spillage would be acceptable in the UH-60. The manufacturer has recommended that use of the 'manual' button before disconnecting the bag would minimize the likelihood of drips occurring. Alternatively, it is probable that a protective cap as described above, would both prevent drips and protect the end of the collecting tube. Another option would be to leave the control unit and bag attached for the duration of a flight, although this is not currently an option for female aircrew due to the pad inflation pressure.

It is worth noting that the HH-60 pilot who had flown with the device noted no tube snagging issues or drips (personal communication, March 15, 2013). However, it is worth noting that he used only the polymer-filled bag, as the re-usable bag was not deemed appropriate due to the risk of in-flight spillage.

Both female participants reported a sensation of "not being totally dry" after use of the system in the aircraft. Suggestions from the manufacturer to minimize this include proper positioning of the pad, and conducting a 'pelvic tilt' whilst holding the manual button.

In the AH-64 integration, a potential for tube snagging was noted between the seat and the airframe in the front cockpit, when the seat was in the lowest position. In the rear cockpit sharp edges beneath the seat could potentially cause damage to the collecting bag. The collecting tube and bag could also be trapped and damaged during raising and lowering of the seat. However, this activity would be unlikely to occur in flight whilst the bag is connected. As with the UH-60, these issues could be overcome by the combination of using a shorter tube and polymer-filled collecting bags.

In the CH-47, the only integration issues related to the 4-point harness and lap belt design which reduced comfort. However, this was deemed acceptable by the participant.

Conclusion

In summary, the AMXDmax® was rated as acceptable or better in all phases of this assessment. The device will not accommodate all anthropometric sizes, but should fit 90% of male aircrew and up to 95% of female aircrew. The key integration issues concerned the

potential for collecting bag damage and rupture in both the UH-60 and AH-64, and also the potential for drips onto under-seat electronics in the UH-60. These issues could potentially be addressed with enhanced training and operating procedures. However, consideration should be given to assessing the system with the 12-inch collecting tube and the polymer-filled disposable urine collection bag. A further refinement to reduce female pad inflation pressure would potentially improve utility for U.S. Army rotary aircrew.

Recommendations

a. The AMXDmax® is a suitable urine collection device in principle for use on U.S. Army UH-60, CH-47 and AH-64 aircraft, by both male and female aircrew in full combat ALSE.

b. Although use of the AMXDmax® is quite intuitive, a training and familiarization package will be required to optimize performance.

c. Some male users may require a larger size of A2CU pant to accommodate the increased bulk of the AMXDmax®.

d. A repeat integration assessment should be conducted using 12-inch collecting tubes.

e. Polymer-filled disposable collecting bags, although more expensive, would be more appropriate for rotary operations.

f. The use of a lower inflation pressure in the female pad is reported to be feasible and should be considered.

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Appendix A.

Questionnaire.

AMXD USER QUESTIONNAIRE

Contact Information

Volunteer Name:	CREW POSITION:	DATE:
EMAIL:	PHONE:	

Ergonomics

Gender:	Height (inches):	Weight (lbs):

Mission Information

Aircraft:

Mission Type: a. Simulator……..…..**YES NO**

b. Aircraft integration…….…**YES NO**

Time Durations (hrs)

Total Flight Duration:

Circle all applicable boxes for equipment worn:

Standard flight suit (A2CU)	Yes	No
Air Warrior Vest Gen II	Yes	No
Air Warrior Vest Gen III	Yes	No
Flight Gloves	Yes	No
HGU-56/P flight helmet	Yes	No
Properly worn extraction harness	Yes	No
Cotton T-Shirt	Yes	No
Cotton Under Shorts	Yes	No
Clear Visor Down	Yes	No
Smoked Visor Down	Yes	No

Please circle a response and explain your answer:

1. Did you observe anything about the AMXD that might jeopardize the safety of the mission? **YES NO**
If yes, give details:

2. Were there any problems associated with the use of the AMXD with the life support equipment combination worn? **YES NO**
If yes, please explain:

3. Did any components of the AMXD fail to perform as intended? **YES NO**
If yes, please explain:

4. Did any of the AMXD components interfere with any preflight or cockpit movement? **YES NO**
If yes, give details:

5. Did you use the AMXD while in the Simulator? **YES NO**
If yes, how many times?

6. Did you have to loosen or remove restraint system(s) to use the AMDX? **YES NO**
Comments:

7. Was it difficult to access or securely stow the pump, hose, or disposable bag? **YES NO**
If yes, which component and why?

8. During the flight did you experience any discomfort associated with the AMXD? **YES NO**
Comments:

9. Did you experience any difficulty relaxing/voiding your bladder in the AMXD cup or pad?

Rate the comfort ability and functionality of the AMXD max extender device

Criteria	Completely Unacceptable	Unacceptable with Recommendation of Improvement	Acceptable	Completely Acceptable No Improvement Needed	N/A
Ease of use of the AMXD Comments:	☐	☐	☐	☐	☐
Comfort of the AMXD cup during flight Comments:	☐	☐	☐	☐	☐
Reliability in urine collection Comments:	☐	☐	☐	☐	☐
The impact of the system on situation awareness Comments:	☐	☐	☐	☐	☐
Adequacy of training Comments:	☐	☐	☐	☐	☐
Fit Comments:	☐	☐	☐	☐	☐
Ease of changing bags during flight Comments:	☐	☐	☐	☐	☐

9. Please provide any additional information you feel we should have to properly evaluate the AMXD? **YES NO**

10. Would you wear the AMXD in the field? **YES NO**
Comments:

11. Additional Comments:

Appendix B.

Generic integration assessment protocol.

1. Subject details

Surname		Forename	
Rank			

2. Assessment

Date			Aircraft type and mk	
Assessed at				
Subject matter experts	IP		Medical officer 1	
			Medical officer 2	
	Crew chief		Other specialist *(SE/engineer/armourer)*	
Crew/seat position assessed				

3. Aircrew Life Support Equipment worn

		Type	Size
a	Helmet		
b	Mask		
c	Spectacles (if worn)		
d	NVG (if worn)		
e	Flying coverall or combat clothing		
f	Immersion suit (if worn)		
g	Survival vest		
h	Life preserver		
i	Armour plate / fragmentation vest *(Note front, rear and/or other plates worn)*		
j	Boots		

Other equipment non-standard or trial (specify):

4. Dressing and undressing

		Satisfactory	Unsatisfactory
a	Any difficulty or restriction in donning / doffing clothing or AEA?		
b	Neck mobility		
c	Upper limb mobility		
d	Back mobility		
e	Hip mobility		
f	Lower limb mobility		

5. Walk out and entry

(Note: This assessment must examine the normal activities conducted by aircrew during pre-flight. This may include crouching or crawling under the airframe, reaching into recesses or climbing the aircraft structure. Guidance should be sought from the assisting aircrew).

Q. Are any difficulties or restrictions experienced during normal access to the aircraft? In particular, crouching, reaching under airframe or climbing into or out of the cockpit.			
		Satisfactory	Unsatisfactory
a	Pre-flight checks and walk-around		
b	Access to hatches, etc		
c	All methods of access to aircraft acceptable (including land away and emergency)?		

6. Strapping in procedures

(Note: Aircrew should adjust the seat to the correct design eye point and this should be used for all remaining assessment serials. Guidance should be sought from the assisting aircrew).

Q. Are there any difficulties or restrictions in achieving the following?			
		Satisfactory	Unsatisfactory
a	Seat adjustment – rake, height, fore/aft		
b	Rudder pedal adjustment		
c	Connection of lanyards, communication leads or man-mounted avionic systems		
d	Attaching and adjusting restraint harness (including parachute if applicable)		

e	Connection of breathing gas supply		
f	Connection of arm or leg restraint lines		
g	Adjustment of ALSE for comfort including access to pockets used in flight		

7. Structural clearance

Q. Is there enough space for the individual within the aircraft for normal working during a crash or in the event of emergency egress? *The following areas may need to be examined:*			
		Acceptable	Unacceptable
a	Stature. *Is individual able to access, egress and work within the environment?*		
b	Sitting height. *Consider canopy clearance, helmet/headbox position, helmet/aircraft overhead panel interactions.*		
c	Buttock-knee / buttock-heel. *Clearance to instrument panel or console. Note any visual obscuration caused by thighs, ability to comfortably place feet on controls and space within leg tunnels (caution feet > size 12).*		
d	Bideltoid breadth (shoulder breadth). *Check clearance to cockpit sizes, access, egress and ability to fit through emergency escape hatches.*		
e	Stomach depth. *Can the harness be secured with most bulky ALSE?* *Does stomach impact on structure, equipment or controls during movement?* *Is subject able to egress through all emergency escape hatches?*		

8. Vision

(Note: Adequate vision of the internal and external environment must be demonstrated to the satisfaction of the medical officer and aircrew subject matter expert).

		Acceptable	Unacceptable
Internal:			
a	Basic flight instruments / symbology		
b	Weapons systems / sighting systems		
c	Emergency warning panel		

d	Comms / nav equipment			
e	Side, centre or overhead panels			
f	Rear crew / other crew, if applicable			
External:				
Note extremes of vision on airframe or outside and confirm acceptability with IP.	Look out scan:			
	g	- Left		
	h	- Right		
	i	- Above		
	j	- Below		
	k	- Behind		

9. Workplace Assessment

(Note: This is required to demonstrate that the aircrew can safely carry out all the actions required to operate the aircraft or equipment within their area of responsibility. Guidance should be taken from the IP or training crew chief).

		Seat harness locked	Seat harness in go forward mode
a	Can the subject reach all the controls to the right?		
b	Can the subject reach all the controls to the left?		
c	Can the subject reach all the controls above?		
d	Can the subject reach all the controls below?		
Note For handling pilots, check all flying controls under the direction of IP and note where restrictions occur.			
Note Check ability of subject to conduct other duties expected of their trade at the workplace under the guidance of IP/crew chief. Make notes / take photographs as required.			

10. Emergency egress

(Note: This is required to demonstrate that aircrew can escape unaided in the event of an emergency. However, this assessment should be done in such a manner as to avoid both injury to the aircrew and structural damage to the aircraft. There is no need to remove escape hatches or jettison doors. Guidance should be taken from the IP/crew chief).

		Satisfactory	*Unsatisfactory*
All aircraft			
a	Harness release		
b	Release of other equipment		
c	Clearance of escape route, operating emergency handles/levers		
d	Egress, primary escape route		
e	Egress, secondary escape route		
f	Egress through emergency panels/openings, if appropriate		

11. Comments

12. Recommendation

Recommendation:	Acceptable	Unacceptable
	(Delete as appropriate)	

Appendix C.

Follow-up questionnaire.

AMXD USER QUESTIONNAIRE

Contact Information
Volunteer Name:

Mission Information
Aircraft: Mission Type:

Time Durations (hrs)
Total Flight Duration:

Please Circle response and explain your answer:

1. Did you experience any adverse events (skin irritation/rash or breakdown, Urinary Tract Infection (UTI), yeast infection, etc.) after using the AMXD device? **YES** NO
If yes, please explain:

2. Did you experience any other problems with the wear of the AMXD max extender device that USAARL personnel should be concerned with? **YES NO**

3. What was your overall opinion of the AMXD device?

4. Would you wear the AMXD device during missions in the field? **YES NO**

5. Did you receive any medical treatment due to the use of the AMXD? **YES NO**
If yes, please explain:

6. Additional Comments:

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U.S. Army Aeromedical Research Laboratory
Fort Rucker, Alabama, 36362-0577
www.usaarl.army.mil

U.S. Army Medical Research and Materiel Command